• Meta-Analysis •

Clinical outcomes of small incision lenticule extraction versus femtosecond laser-assisted LASIK for myopia: a Meta-analysis

Huan Yan[1], Li-Yan Gong[1], Wei Huang[1], Yan-Li Peng[2,3]

[1]Department of Ophthalmology, the Second Affiliated Hospital of Chongqing Medical University, Chongqing Medical University, Chongqing 400010, China
[2]Department of Ophthalmology, Chongqing Aier-Mega Eye Hospital, Aier Eye Hospital Group, Chongqing 400060, China
[3]Aier School of Ophthalmology, Central South University, Changsha 410000, Hunan Province, China
Correspondence to: Yan-Li Peng. Department of Ophthalmology, Chongqing Aier-Mega Eye Hospital, Aier Eye Hospital Group, Chongqing 400060, China. ysl818106@sina.cn
Received: 2017-04-25 Accepted: 2017-06-07

Abstract

• AIM: To evaluate the possible differences in visual quality between small incision lenticule extraction (SMILE) and femtosecond laser *in situ* keratomileusis (FS-LASIK) for myopia.

• METHODS: A Meta-analysis was performed. Patients were from previously reported comparative studies treated with SMILE versus FS-LASIK. The PubMed, EMBASE, Cochrane, Web of Science and Chinese databases (*i.e.* WANFANG and CNKI) were searched in Nov. of 2016 using RevMan 5.1 version software. The differences in visual acuity, aberration and biomechanical effects within six months postoperatively were showed. Twenty-seven studies including 4223 eyes were included.

• RESULTS: No significant differences were observed between SMILE and FS-LASIK in terms of the proportion of eyes that lost one or more lines of corrected distance visual acuity after surgery (*P*=0.14), the proportion of eyes achieving an uncorrected distance visual acuity of 20/20 or better (*P*=0.43), the final refractive spherical equivalent (*P*=0.89), the refractive spherical equivalent within ±1.00 diopter of the target values (*P*=0.80), vertical coma (*P*=0.45) and horizontal coma (*P*=0.06). Compared with the FS-LASIK group, total higher-order aberration (*P*<0.001) and spherical aberration (*P*<0.001) were higher and the decrease in corneal hysteresis (*P*=0.0005) and corneal resistance factor (*P*=0.02) were lower in the SMILE group.

• CONCLUSION: SMILE and FS-LASIK are comparable in efficacy, safety and predictability for correcting myopia. However, the aberration in the SMILE group is superior to that in the FS-LASIK group, and the loss of biomechanical effects may occur less frequently after SMILE than after FS-LASIK.

• KEYWORDS: Meta-analysis; small incision lenticule extraction; femtosecond laser *in situ* keratomileusis; myopia
DOI:10.18240/ijo.2017.09.17

Citation: Yan H, Gong LY, Huang W, Peng YL. Clinical outcomes of small incision lenticule extraction versus femtosecond laser-assisted LASIK for myopia: a Meta-analysis. *Int J Ophthalmol* 2017; 10(9):1436-1445

INTRODUCTION

Femtosecond laser *in situ* keratomileusis (FS-LASIK) has been the most common corneal refractive surgery and has proved to be effective, safe and predictable for treating myopia[1]. However, there is some problems to limit the application of FS-LASIK, which includes the risk of flap-related complications and dry eye[2-3].

Small incision lenticule extraction (SMILE) becomes a new option for myopic patients and the corneal flap production is replaced by removing the corneal stroma lenticule from a minimized incision to reduce the complications of corneal flap and dry eye since 2011[4-5]. Recent studies have indicated that there is less impairment of the biomechanical effects and more corneal nerves are preserved when treated with SMILE compared with FS-LASIK because of the complement of the anterior cornea, which can reduce the incidence of dry eye[6-8]. However, there is no wavefront-guided individual treatment to reduce the production of aberration in SMILE.

Recent clinical studies have contrasted some pros and cons between SMILE and FS-LASIK to treat myopia[9-13], but there were several different conclusions regarding the postoperative visual quality between the two procedures, especially in terms of the biomechanical effects[9,14-16]. Currently, several Meta-analyses have only investigated the clinical outcome differences in visual acuity and dry eye between SMILE and FS-LASIK[17-19], which is insufficient for the evaluation of the two types of surgeries. Therefore, the purpose of our study was to review mass of relative literatures for exploring the benefits

in visual acuity, aberration, biomechanical effects and contrast sensitivity between SMILE and FS-LASIK.

MATERIALS AND METHODS

We conduct the Meta-analysis in accordance with a prepared protocol, following the generally accepted recommendations[20-21].

Search Strategy Two reviewers independently searched PubMed, EMBASE, Cochrane, Web of Science and Chinese databases (WANFANG and CNKI) up to November 20th, 2016. The search keywords were included: "myopia", "small-incision lenticule extraction" or "SMILE" and "FS-LASIK" or "femtosecond" or "laser *in situ* keratomileusis". No date or language restrictions were used for the research. We scanned the titles and abstracts, retrieved relative full studies and involved the articles in accordance with our inclusion criteria. Any disagreement between the reviewers was resolved by discussion.

Inclusion Criteria The following selection criteria was included: 1) prospective randomized controlled trials (RCTs) and non-randomized comparative trials; 2) adults with any degree of myopia or myopic astigmatism without systemic or ocular disease; 3) patients treated with the corneal surgery (SMILE or FS-LASIK); 4) the follow-up period no less than 3mo; 5) original clinical articles with independent data was selected.

Outcome Measures The primary outcome parameters were efficacy, safety, and predictability. The efficacy measure was the proportion of eyes achieving an uncorrected visual acuity (UCVA) of 20/20 or better. The safety measures were the percentage of eyes losing one or more lines of best spectacle corrected distance visual acuity (BSCVA) and the postoperative spherical equivalent (SE). The refractive SE within ±1.00 diopter (D) of the target refraction was as the measure of predictability.

The secondary outcomes were aberration, biomechanical effects and contrast sensitivity. Aberration included total higher-order aberration (tHOA), spherical aberration, horizontal coma and vertical coma, and biomechanical effects included corneal hysteresis (CH) and corneal resistance factor (CRF). The follow-up period ranged from three to six months, and data were extracted and analyzed from the included studies.

Data Extraction and Quality Assessment The data extraction and quality assessment were independently finished by two reviewers, and the following information was extracted: the first author, design, year, country, enrolled eyes number, preoperative SE, follow-up time and scores of assessment. The Jadad scale[22] was used to assess the RCTs, while the Newcastle-Ottawa scale (NOS)[23] was adopted to evaluate the cohorts. Randomization, blinding, and participant withdrawal/dropout were the parameters of the Jadad scale, and the scores of Jadad scale ranged from minimum of 0 (low quality) and maximum of 5 (high quality). Each one point was allocated for the parameters of the Jadad scale respectively and additional one point was obtained when randomization and blinding were appropriate. The NOS contains the following three main areas of assessment: selection quality, comparability, and outcome measures. The study was considered high quality when scoring >3 points in the Jadad scale or scoring >6 points in the NOS.

Statistical Analysis The Meta-analysis was completed with the RevMan software (version 5.2). The mean difference (MD) was used for continuous outcomes, and the odds ratio (OR) was calculated for dichotomous outcomes. The corresponding 95% CI was used for summary estimates, and statistically significant was a $P<0.05$.

The Chi-square and I^2 statistics were used to assess heterogeneity. The fixed effect model (FEM) was used without significant heterogeneity. However, the random effect model (REM) was used when heterogeneity was obvious ($P<0.10$ or I^2 was >50%).

The robustness of the results was evaluated with sensitivity analysis, which was performed by excluding the individual studies one by on to assess its influence on the pooled estimation. Begg's and Egger's tests were adopted to estimate publication bias using STATA[24-25] (version 12.0).

RESULTS

Search Results A total of 201 relative studies were selected through the electronic databases. After titles and abstracts were screened, 123 studies were excluded and 19 studies were found ineligible for inclusion after a systematic review. Finally, 2 RCTs[10,12] and 25 cohorts[7,9,13-16,26-44] were involved. The reasons to exclude studies were as follows: 2 studies did not have qualifying interventions, 1 study did not have measurable outcomes, 2 studies were simple letters or commentaries, 3 studies were experiments, 5 studies were duplicates, and 6 studies did not consist with inclusion criteria.

Study Characteristics and Quality The characteristics and the quality assessment of the included studies were summarized in Tables 1, 2. A total of 4223 eyes were included, of which 1928 eyes (45.65%) treated with SMILE and 2295 eyes (54.35%) treated with FS-LASIK. The randomization measures that were used were inadequate in the RCTs[10,12], and there was no blinding of the surgeons or patients. When compared with non-randomized cohort studies, the following factors were not significantly different between groups within the studies: age, gender, preoperative SE, aberration, CH or CRF[7,9,13-16,26-44]. Only eleven studies had six months of follow-up[7,9,14-15,28,30,33,37-39,44]. Therefore, both RCT studies were considered low quality (scoring<3) according to the standard of Jadad scale, and twenty-four non-randomized comparative studies scored of high quality (NOS≥6) except for Shen *et al*[42] 2014 (NOS=5).

Primary Outcomes

Uncorrected visual acuity of 20/20 or better Seven publications demonstrated percentage of eyes with UCVA of 20/20 or

Table 1 Characteristics of included studies contrasting SMILE to FS-LASIK mean±SD

Study	Design	Year	Country	SMILE group		FS-LASIK group		Follow-up (mo)	Jadad	NOS
				Eyes (*n*)	Preoperative	Eyes (*n*)	Preoperative			
Hu *et al*[26]	CT (prospective)	2013	China	82	-4.91±1.29	82	-6.29±2.37	3	-	7
Hu *et al*[27]	CT (prospective)	2013	China	83	-4.91±1.29	94	-6.26±2.33	3	-	6
Lin *et al*[40]	CT (prospective)	2013	China	33	-4.81±1.47	37	-5.56±2.08	3	-	7
Lin *et al*[13]	CT (prospective)	2014	China	60	-5.13±1.75	51	-5.58±2.41	3	-	7
Denoyer *et al*[37]	CT (prospective)	2015	France	30	-4.65±2.38	30	-4.42±1.78	6	-	8
Wang *et al*[14]	CT (retrospective)	2016	China	50	-7.60±1.12	56	-7.68±1.19	3	-	7
Sefat *et al*[41]	CT (prospective)	2016	Germany	43	-3.81±0.95	26	-3.65±1.12	3	-	6
Wu *et al*[7]	CT (prospective)	2014	China	40	-5.71±1.19	40	-5.80±1.14	6	-	8
Li *et al*[30]	CT (retrospective)	2014	China	22	-4.91±0.90	43	-5.48±2.09	6	-	6
Li *et al*[28]	CT (prospective)	2014	China	72	-6.04±1.80	70	-5.94±1.73	6	-	8
Li *et al*[38]	CT (retrospective)	2016	China	97	-5.33±1.46	96	-5.61±1.75	6	-	8
Xu and Yang[44]	CT (prospective)	2014	China	81	-5.70±1.70	97	-5.80±2.01	6	-	8
Li *et al*[29]	CT (retrospective)	2016	China	40	-7.89±0. 87	40	-7.31±0.66	3	-	6
Ye *et al*[33]	CT (retrospective)	2014	China	170	-5.03±1.89	88	-5.43±2.32	6	-	8
Shen *et al*[42]	CT (retrospective)	2014	China	17	-6.48±1.22	17	-8.71±2.02	3	-	5
Ang *et al*[35]	CT (prospective)	2015	Singapore	172	-5.71±2.11	688	-5.73±2.06	3	-	7
Wu and Wang[16]	CT (retrospective)	2016	China	73	-5.80±1.35	52	-5.46±1.08	3	-	7
Li *et al*[39]	CT (retrospective)	2015	China	55	-5.74±1.39	51	-6.18±1.61	6	-	8
Zhang *et al*[34]	CT (retrospective)	2016	China	95	-5.34±1.55	69	-5.01±1.95	3	-	6
Wu and Wang[43]	CT (retrospective)	2015	China	75	-5.49±1.35	75	-5.56±1.76	3	-	8
Chan *et al*[36]	CT (prospective)	2016	China	54	-5.23±1.96	57	-5.82±2.60	3	-	7
Qiao *et al*[31]	CT (prospective)	2015	China	188	-5.24±1.85	184	-5.24±1.72	3	-	7
Wu *et al*[32]	CT (prospective)	2015	China	34	-6.86±0.84	29	-7.20±0.82	3	-	7
Xia *et al*[15]	CT (prospective)	2016	China	69	-5.04±2.32	59	-5.13±1.36	6	-	8
Agca *et al*[9]	CT (prospective)	2014	Turkey	30	-3.62±1.79	30	-3.71±1.83	6	-	8
Liu *et al*[10]	RCT	2016	China	113	-5.22±1.70	84	-5.18±1.93	6	1	-
Ganesh and Gupta[12]	RCT	2014	India	50	-4.95±2.09	50	-3.54±1.26	3	1	-

SMILE: Small incision lenticule extraction; FS-LASIK: Femotosecond laser *in situ* keratomileusis; RCT: Randomized comparative trial; CT: Comparative trial; SE: Spheriacl equivalent.

better, and no significant differences were found between the SMILE and FS-LASIK groups within 6mo (OR 0.77; 95% CI: 0.54, 1.09; *P*=0.14; Figure 1)[10,12-13,15,31,35-36].

Losing one or more lines of best spectacle-corrected visual acuity Seven studies reported no significant differences were found in the percentage of eyes losing one or more lines of BSCVA between the two groups at the end of follow-up time (OR 1.22; 95% CI: 0.74, 2.03; *P*=0.43; Figure 2)[10,13,15,27,31,36,44].

Postoperative mean refractive spherical equivalent Eleven studies indicated there was no significant difference of the postoperative mean refractive SE outcomes between SMILE and FS-LASIK groups (MD 0.00; 95% CI: -0.04, 0.05; *P*=0.89; Figure 3)[10,12-13,27,30,34-37,41-42].

Postoperative refraction within ±1.0 D of the target refraction Six studies reported no significant difference was found in the postoperative refraction within ±1.0 D of the target refraction between SMILE and FS-LASIK groups (OR 0.91; 95% CI: 0.43, 1.93; *P*=0.80; Figure 4)[10,13,27,31,36,44].

Secondary Outcomes

Aberration Ten studies reported the postoperative aberration at the follow-up times within 6mo. The forest plot showed that tHOA (MD -0.47; 95% CI: -0.61, -0.33; *P*<0.00001; Figure 5)[16,26,28,31,33,39,43-44] and spherical aberration (MD -0.64; 95% CI: -0.88, -0.39; *P*<0.00001; Figure 6)[10,16,26,28,31,33,39-40,43-44] were lower in the SMILE group than that in FS-LASIK. No significant difference was found in either the horizontal coma (MD 0.11; 95% CI: -0.06, 0.28; *P*=0.19; Figure 7)[10,16,26,28,33,40,43-44] or the vertical coma (MD -0.10; 95% CI: -0.36, 0.16; *P*=0.45; Figure 8)[26,28,33,39,43] between the two groups. A sensitivity analysis was conducted because of the apparent heterogeneity

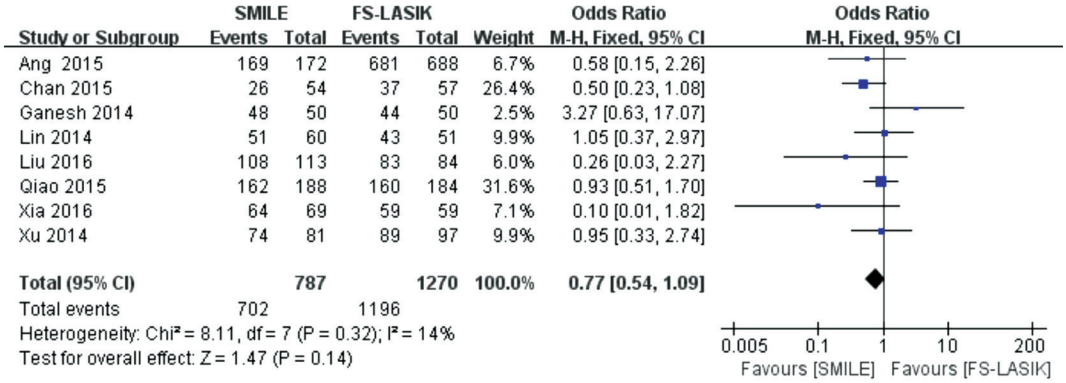

Figure 1 Proportion of eyes achieving UCVA of 20/20 or better after SMILE versus FS-LASIK within 6mo.

Table 2 NOS for non-randomized comparative studies

Study	Selection	Comparability	Outcome	Sum of score
Hu *et al*[26]	3	2	2	7
Hu *et al*[27]	3	1	2	6
Lin *et al*[40]	3	2	2	7
Lin *et al*[13]	3	2	2	7
Denoyer *et al*[37]	3	2	3	8
Wang *et al*[14]	3	2	2	7
Sefat *et al*[41]	3	1	2	6
Wu *et al*[7]	3	2	3	8
Li *et al*[30]	3	2	3	8
Li *et al*[28]	3	1	2	6
Li *et al*[38]	3	2	3	8
Xu and Yang[44]	3	2	3	8
Li *et al*[29]	3	2	3	8
Ye *et al*[33]	3	1	2	6
Shen *et al*[42]	3	2	3	8
Ang *et al*[35]	3	-	2	5
Wu and Wang[16]	3	2	2	7
Li *et al*[39]	3	2	2	7
Zhang *et al*[34]	3	2	3	8
Wu and Wang[43]	3	1	2	6
Chan *et al*[36]	3	2	3	8
Qiao *et al*[31]	3	2	2	7
Wu *et al*[32]	3	1	2	6
Xia *et al*[15]	3	2	3	8
Agca *et al*[9]	3	2	3	8

The total scores of NOS ranged from minimum of 0 (low quality) and maximum of 9 (high quality), basing on the following standards: patient selection methodology (points ranged from 1 to 4), comparability of the study groups (points ranged from 1 to 2) and outcomes measures (points ranged from 1 to 3).

in the spherical aberration, the horizontal coma and the vertical coma (the value of I^2>50%). In the spherical aberration and vertical coma outcomes, a apparent heterogeneity (I^2>50%) among the remaining studies didn't reduce when each study was excluded in turn and the results of the previous analyses wasn't changed by any exclusion. Additionally, the heterogeneity (I^2 from 94% to 49%) of postoperative horizontal coma significantly decreased when the Li *et al*'s[39] study was excluded, which did not influence the previous analyses.

Biomechanical effects Six studies showed significant differences were found in CH (MD 0.46; 95% CI 0.20, 0.72; *P*=0.0005; Figure 9) and CRF (MD 0.67; 95% CI 0.38, 0.96; *P*<0.00001; Figure 10) between the two groups. The exclusion of the Agca *et al*[9] made I^2 reduce from 69% to 40%, but did little influence on the results of CRF (MD 0.48; 95% CI: 0.21, 1.27; *P*=0.02).

Contrast sensitivity Four studies reported changes in contrast sensitivity after SMILE and FS-LASIK[10,12,40,44]. Liu *et al*[10] indicated that the contrast sensitivity recovered to the preoperative level later in the SMILE group than that in FS-LASIK. Regarding the follow-up time, several reports[40,44] suggested that contrast sensitivity was better in the SMILE group than in FS-LASIK, particularly at higher spatial frequencies[12]. The changes in contrast sensitivity are presented in Table 3.

Publication Bias No publication bias was apparent using Begg's tests (*P*=0.142 to 0.881) and Egger's test (*P*=0.106 to 0.926) (Table 4).

DISCUSSION

In this Meta-analysis, SMILE achieved similar efficacy, safety and predictability as FS-LASIK within a 6mo follow-up time, and the outcomes of horizontal coma and vertical coma were not significantly different between the two surgeries. Additionally, the increase in tHOA and spherical aberration in the SMILE group was lower than that in the FS-LASIK group. In addition, the decrease in the CH and CRF was greater in the FS-LASIK group compared with the SMILE group, which aided in the investigation of the fewer impact of biomechanical effects in the SMILE group. Most studies demonstrated that the contrast sensitivity in SMILE was superior to that in FS-LASIK. Currently, three Meta-analyses have been published, all of which focused on efficacy, safety, predictability, dry eye and central corneal sensitivity. Therefore, our study is the first study to compare the clinical outcomes of aberration, biomechanical effects and contrast sensitivity between the

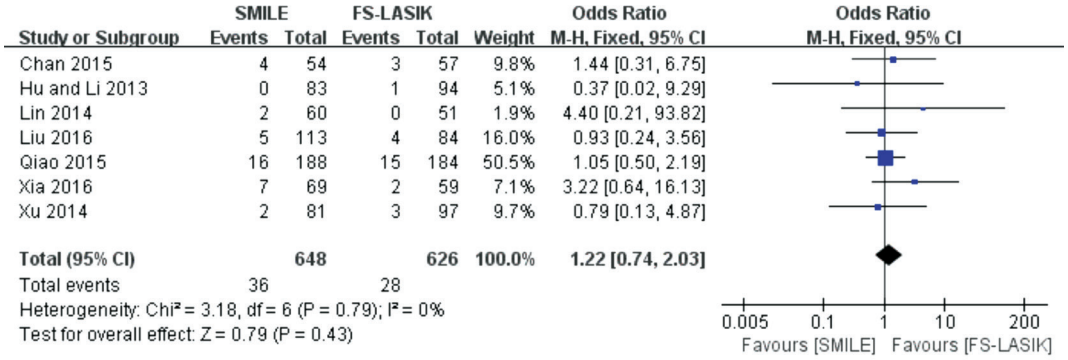

Figure 2 Proportion of eyes losing one more lines of BSCVA after SMILE versus FS-LASIK within 6mo.

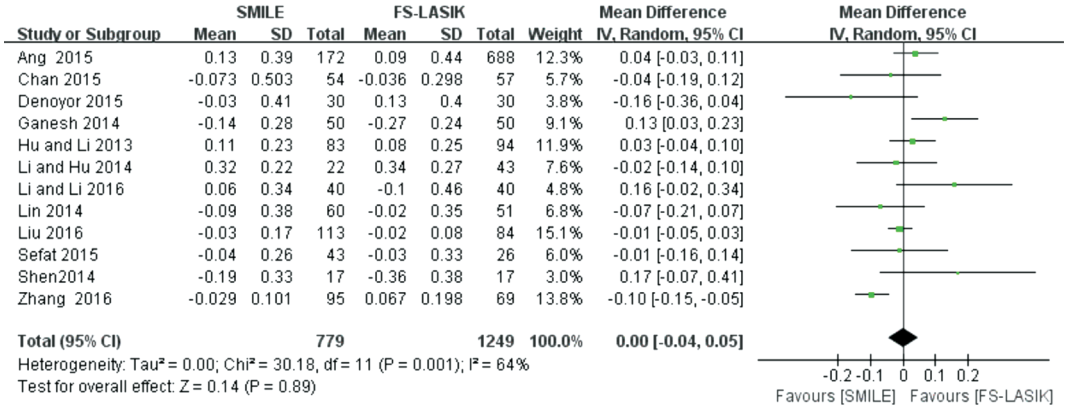

Figure 3 Postoperative mean refractive SE after SMILE versus FS-LASIK within 6mo.

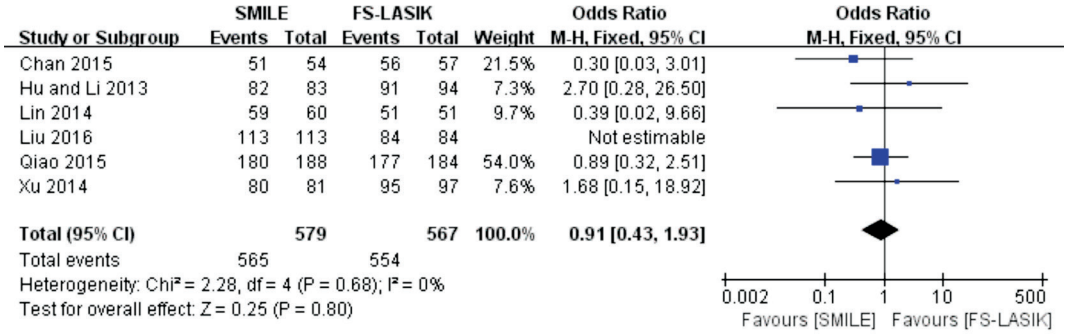

Figure 4 Proportion of eyes with postoperative refraction within ±1.0 D of target after SMILE versus FS-LASIK within 6mo.

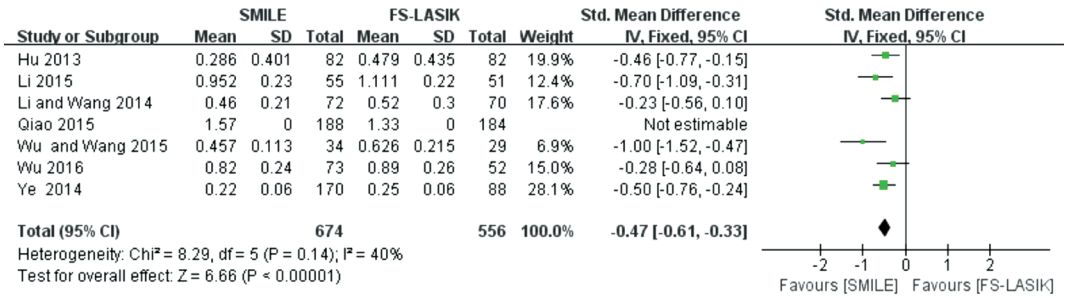

Figure 5 tHOA after SMILE versus FS-LASIK within 6mo.

SMILE and FS-LASIK techniques using a Meta-analysis with more related studies included.

Because of the differences in the details of the reviewed studies, we had difficulty in extracting data and summarizing the data. We included all data that were consistent with our inclusion criteria and interpreted the clinical outcomes. When heterogeneity was observed among the studies, a sensitivity analysis was conducted. In addition, we used Begg's rank correction test and Egger's linear regression test to determine the publication bias. A major difficulty was the different measurements of aberration, biomechanical effects and contrast sensitivity. When detecting aberration and

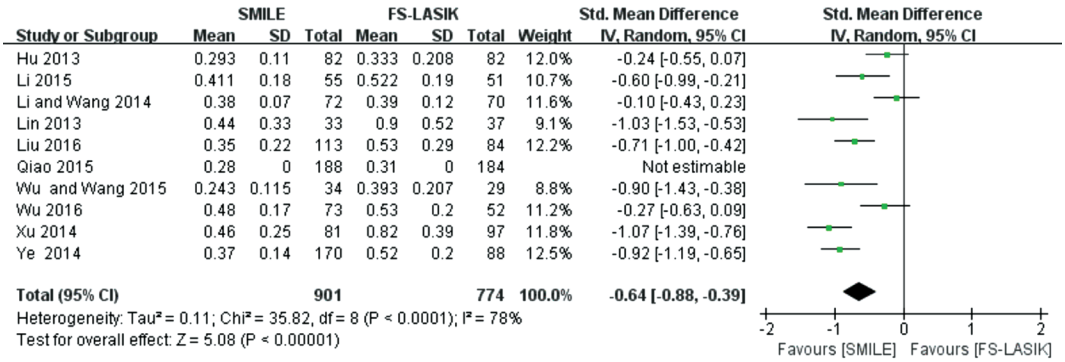

Figure 6 Spherical aberration after SMILE versus FS-LASIK within 6mo.

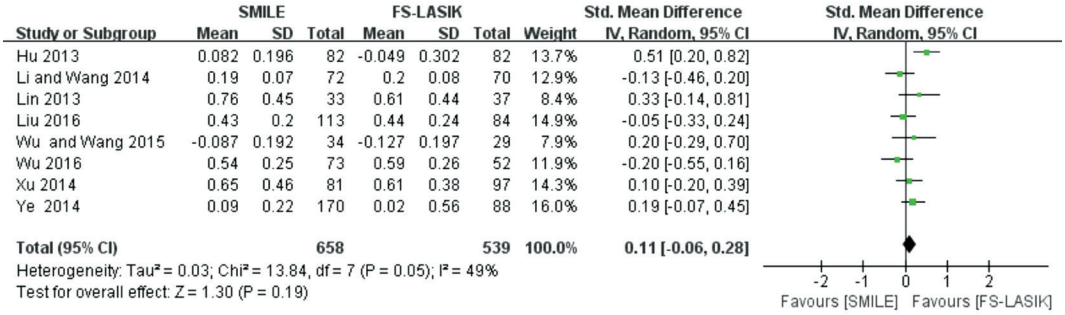

Figure 7 Horizontal coma after SMILE versus FS-LASIK within 6mo.

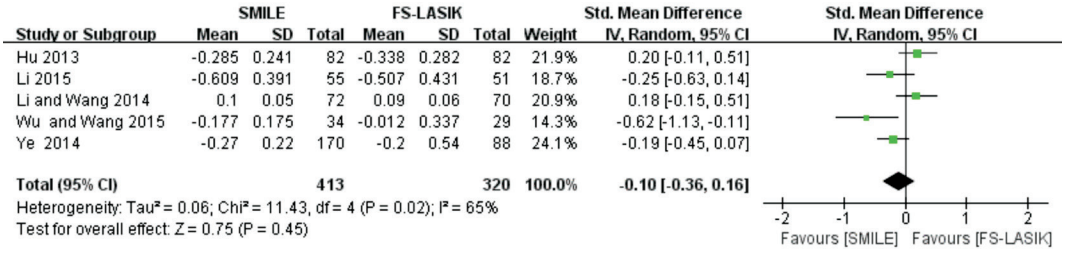

Figure 8 Vertical coma after SMILE versus FS-LASIK within 6mo.

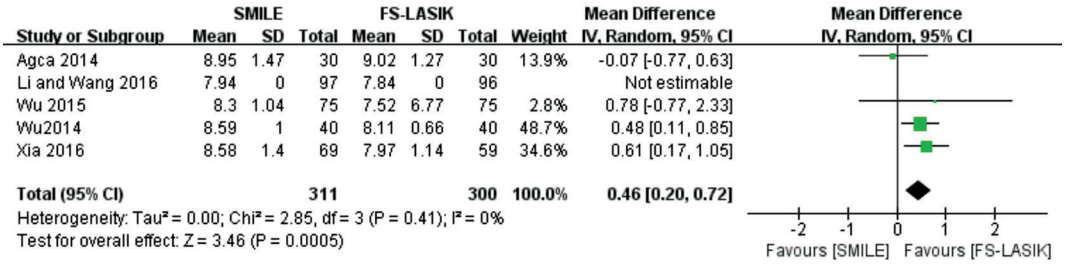

Figure 9 CH after SMILE versus FS-LASIK within 6mo.

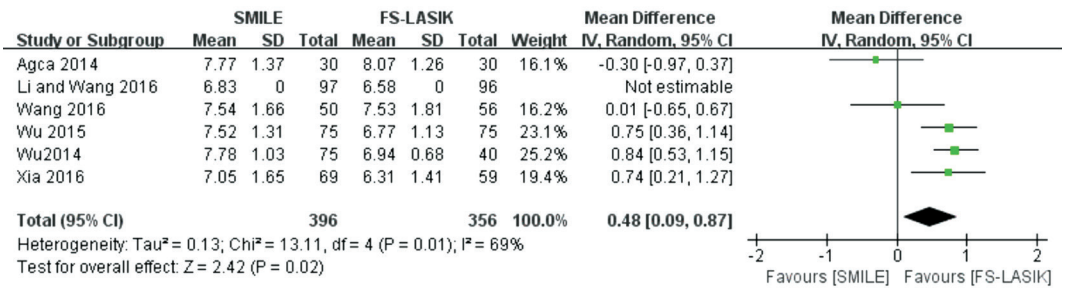

Figure 10 CRF after SMILE versus FS-LASIK within 6mo.

biomechanical effects, these studies used a different wavefront analyzer or biomechanical instrument, which may account for the significant difference. Therefore, we selected the parameters of the whole cornea aberration at 6 mm in diameter and the ocular response analyzer for the biomechanical effects. Another difficulty was the diverse variation in the follow-up

Table 3 Changes in contrast sensitivity

References	Method	Findings
Ganesh *et al*[12]	Measured using the FACT chart	At day 1, contrast sensitivity was better in FS-LASIK group than SMILE group at the 1.5, 3, 6, 12 and 18 cpd , but by 15d and 3mo, contrast sensitivity was better in SMILE group than FS-LASIK group, particularly at higher spatial frequencies (18 cpd).
Lin *et al*[40]	Measured using the CGT-1000	Contrast sensitivity was better in SMILE group than FS-LASIK group at the 1.0, 1.7, and 4.2 cpd without glare and at 2.6, 4.2 and 6.6 cpd with glare after 1mo. And it was better in SMILE group than FS-LASIK group at the 1.7 and 4.2 cpd without glare and at 1.7 cpd with glare after 3mo.
Xu and Yang[44]	Measured using the CGT-1000	Contrast sensitivity was better in SMILE group than FS-LASIK group at 6mo postoperatively.
Liu *et al*[10]	Measured using the CSV-1000E	In the SMILE group, the contrast sensitivity at spatial frequencies of 3 cpd and 6 cpd under different lighting conditions recovered to the preoperative level at 1wk postoperatively, but 12 cpd and 18 cpd recovered to the preoperative level at 1mo postoperatively. In the FS-LASIK group, the contrast sensitivity at spatial frequencies of 3, 6, 12, and 18 cpd under different lighting conditions recovered to the preoperative level at 1wk postoperatively

Table 4 The *P* value of Begg's tests and Egger's tests

Outcomes	Begg's tests	Egger's tests
UCVA more than 20/20 or better	0.805	0.657
Losing one or more lines of BSCVA	0.881	0.630
Mean refractive SE	0.784	0.926
Postoperative refraction within ±1.0 D of target	0.142	0.138
tHOA	0.348	0.254
Spherical aberration	0.458	0.466
Horizontal coma	0.211	0.106
Vertical coma	0.327	0.428
CH	0.624	0.900
CRF	0.327	0.344

UCVA: Uncorrected visual acuity; BSCVA: Best spectacle-corrected visual acuity; SE: Spherical equivalent; tHOA: Total higher-order aberration; CH: Corneal hysteresis; CRF: Corneal resistance factor. Publication bias was significant when $P \leq 0.05$ using with Begg's tests and Egger's tests.

times. According to our clinical experience and the associated study[18], the parameters of efficacy, safety, predictability, aberration and biomechanical effects are stable at least three months postoperatively. Thus, the follow-up time of the Meta-analysis was conducted within 6mo.

This Meta-analysis suggested that both SMILE and FS-LASIK are effective, safe and predictable. In terms of efficacy, an examination of the forest plot revealed that no significant differences were detected between the SMILE and FS-LASIK groups relative to the proportions with uncorrected distance visual acuities of 20/20 or better. The I^2 value of UCVA indicated that heterogeneity was not observed among the studies and that the results were analyzed using a fixed effects model. Ang *et al*[35] and Liu *et al*[10] suggested that the results of proportions with uncorrected distance visual acuities of 20/20 or better in the FS-LASIK group were better than in the SMILE group during the 3mo to 6mo, which may be due to the difference in the healing response between both procedures. Agca *et al*[45] reported that eyes treated SMILE have increased corneal backscatter in the interface 3mo after extracted lenticule surgery compared with the FS-LASIK procedure.

In terms of safety, the proportion of eyes losing one or more lines of corrected distance visual acuity in the SMILE group was similar to those in the FS-LASIK group, which suggested that both SMILE and FS-LASIK are safe concerning correction of refraction.

In terms of predictability, we assessed the postoperative mean refractive SE and the proportion of postoperative refraction within ±1.0 D of the target refraction and no significant differences were found between the two groups. Additionally, Ganesh demonstrated that SMILE has greater predictability than FS-LASIK because the refractive lenticule was cut by a femtosecond laser in SMILE rather than by lifting the flap and exposing the stroma in FS-LASIK, which may reduce hydration changes of corneal stroma in SMILE[46-47].

Visual quality is not only visual acuity but also includes aberration and contrast sensitivity. The refractive surgery-induced aberration increased after the surgery following up time point of 6mo. The increasing of tHOA and spherical aberration occurred more in the FS-LASIK group than in the SMILE group. However, there was not an apparent difference in horizontal coma and vertical coma between two groups. Controversially, Wu and Wang[43] reported that the vertical coma was significantly increased after the SMILE surgery, whereas the horizontal coma was significantly increased after FS-LASIK surgery. The postoperative spherical aberration was associated with optical and ablation zones[48]. There is no transition zone for the SMILE procedure, and it achieves a larger ablation zone than the FS-LASIK procedures, which indicated that spherical aberration was lower in SMILE group than that in FS-LASIK group. With regard to the induction of coma, imbalanced corneal healing responses and imbalanced optical changes along the axis were involved[49]. Several studies[50-51] demonstrated that the induction of coma was

caused by decentrations after the SMILE surgery. Whereas, another study[43] reported that weaker wound healing responses occurred in the SMILE group. In brief, more research and further studies are needed to investigate the change of aberration when comparing SMILE with FS-LASIK. Furthermore, the I^2 value of spherical aberration, horizontal coma and vertical coma all showed significant heterogeneity among studies. Thus, a sensitivity analysis was performed, and the results were evaluated using a random effects model. For spherical aberration and vertical coma, the results were analyzed by excluding one study at a time and demonstrated that the heterogeneity did not change and the results of the previous analysis were stable. When excluding Li *et al*[39], the I^2 value decreased, but there was no significant change in the estimated value, which may have been caused by measurement bias.

The refractive surgery-induced biomechanical effects decreased after surgery demonstrated by six reports[9,14-16,38,43]. The data showed a smaller decrease of CH and CRF in the SMILE group than in the FS-LASIK group within 6mo after surgery. Nevertheless, there was significant heterogeneity in CRF by assessing the I^2 value. Sensitivity analysis revealed that the study by Agca *et al*[9] was the source of statistical heterogeneity in the Meta-analysis for the CRF, but the exclusion of the study did not significantly reduce heterogeneity. Agca *et al*[9] involved patients with low to moderate myopia, however, other studies included moderate to high myopia. However, there is no evidence to identify the correlation between the degree of myopia and the change of biomechanical effects between two groups. Moreover, Wang *et al*[14] reported that there was a significant difference between SMILE and FS-LASIK (P=0.096) at the 6mo follow-up, although there was no statistically significant difference in CH. The study of Wang *et al*[14] can sharply increase the heterogeneity among these studies (I^2 from 0 to 94%) and is the reason for excluding the study. Several clinical studies[15-16,43] and mathematical analyses[52-53] demonstrated that the SMILE procedure was superior to the FS-LASIK surgery with respect to the corneal biomechanics. Otherwise, another study[9] found similar biomechanical effects between SMILE and FS-LASIK surgery. Biomechanically, the flapless lenticule extraction technique maximally protects the structural integrity of the cornea and causes less disruption of the peripheral collagen fibers than LASIK[7]. Theoretically, the degree of wound repair is correlated with the inherent strength of the corneal tissues[54]. An *in vivo* study[55] found that refractive lenticule extraction might result in less inflammation and early extracellular matrix deposition than LASIK.

In consideration of contrast sensitivity, it is known that contrast sensitivity is lower after undergoing SMILE and FS-LASIK surgery. Several studies[12,40,44] indicated that contrast sensitivity was better in SMILE group than that in FS-LASIK group except the report of Liu *et al*[10]. Liu *et al*[10] reported that the speed of recovery of contrast sensitivity was due to the different mechanisms of the corneal stromal wound-healing process after both procedures at high spatial frequencies under different lighting conditions. Furthermore, several previous studies have suggested that the decrease in contrast sensitivity was associated with the increase in HOAs[56-57]. However, Stonecipher and Kezirian[58] found that there was no relationship between contrast sensitivity and HOAs.

There are several important limitations in the Meta-analysis. First, most of the studies were from Asia, which may cause publishing bias. Second, extracted data of aberration included various measurements from different wavefront analyzers, which increased the method bias.

In conclusion, SMILE and FS-LASIK are comparably safe, effective and predictable when used for the treatment of myopia. Postoperative aberration and a decrease in biomechanical effects may occur less frequently after SMILE than after FS-LASIK. Contrast sensitivity was better in the SMILE group than in the FS-LASIK group 3-6mo postoperatively. Further randomized, double-blinded, prospective studies with longer follow-up periods are warranted to provide a better understanding of the benefits of SMILE and FS-LASIK.

ACKNOWLEDGEMENTS

Conflicts of Interest: Yan H, None; **Gong LY**, None; **Huang W**, None; **Peng YL**, None.

REFERENCES

1 Vryghem JC, Devogelaere T, Stodulka P. Efficacy, safety, and flap dimensions of a new femtosecond laser for laser *in situ* keratomileusis. *J Cataract Refract Surg* 2010;36(3):442-448.

2 Golas L, Manche EE. Dry eye after laser *in situ* keratomileusis with femtosecond laser and mechanical keratome. *J Cataract Refract Surg* 2011;37(8):1476-1480.

3 dos Santos AM, Torricelli AA, Marino GK, Garcia R, Netto MV, Bechara SJ, Wilson SE. Femtosecond laser-assisted LASIK flap complications. *J Refract Surg* 2016;32(1):52-59.

4 Sekundo W, Kunert KS, Blum M. Small incision corneal refractive surgery using the small incision lenticule extraction (SMILE) procedure for the correction of myopia and myopic astigmatism: results of a 6 month prospective study. *Br J Ophthalmol* 2011;95(3):335-339.

5 Shah R, Shah S, Sengupta S. Results of small incision lenticule extraction: all-in-one femtosecond laser refractive surgery. *J Cataract Refract Surg* 2011;37(1):127-137.

6 Wei S, Wang Y. Comparison of corneal sensitivity between FS-LASIK and femtosecond lenticule extraction (ReLEx flex) or small-incision lenticule extraction (ReLEx smile) for myopic eyes. *Graefes Arch Clin Exp Ophthalmol* 2013;251(6):1645-1654.

7 Wu D, Wang Y, Zhang L, Wei S, Tang X. Corneal biomechanical effects: small-incision lenticule extraction versus femtosecond laser-assisted laser *in situ* keratomileusis. *J Cataract Refract Surg* 2014;40(6):954-962.

8 Demirok A, Ozgurhan EB, Agca A, Kara N, Bozkurt E, Cankaya KI, Yilmaz OF. Corneal sensation after corneal refractive surgery with small incision lenticule extraction. *Optom Vis Sci* 2013;90(10):1040-1047.

9 Agca A, Ozgurhan EB, Demirok A, Bozkurt E, Celik U, Ozkaya A, Cankaya I, Yilmaz OF. Comparison of corneal hysteresis and corneal resistance factor after small incision lenticule extraction and femtosecond laser-assisted LASIK: a prospective fellow eye study. *Cont Lens Anterior Eye* 2014;37(2):77-80.

10 Liu M, Chen Y, Wang D, Zhou Y, Zhang X, He J, Zhang T, Sun Y, Liu Q. Clinical outcomes after SMILE and femtosecond laser-assisted LASIK for myopia and myopic astigmatism: a prospective randomized comparative study. *Cornea* 2016;35(2):210-216.

11 Pinero DP, Teus MA. Clinical outcomes of small-incision lenticule extraction and femtosecond laser-assisted wavefront-guided laser *in situ* keratomileusis. *J Cataract Refract Surg* 2016;42(7):1078-1093.

12 Ganesh S, Gupta R. Comparison of visual and refractive outcomes following femtosecond laser-assisted lasik with smile in patients with myopia or myopic astigmatism. *J Refract Surg* 2014;30(9):590-596.

13 Lin F, Xu Y, Yang Y. Comparison of the visual results after SMILE and femtosecond laser-assisted LASIK for myopia. *J Refract Surg* 2014;30(4):248-254.

14 Wang B, Zhang Z, Naidu RK, Chu R, Dai J, Qu X, Yu Z, Zhou H. Comparison of the change in posterior corneal elevation and corneal biomechanical parameters after small incision lenticule extraction and femtosecond laser-assisted LASIK for high myopia correction. *Cont Lens Anterior Eye* 2016;39(3):191-196.

15 Xia L, Zhang J, Wu J, Yu K. Comparison of corneal biological healing after femtosecond LASIK and small incision lenticule extraction procedure. *Curr Eye Res* 2016;41(9):1202-1208.

16 Wu W, Wang Y. Corneal higher-order aberrations of the anterior surface, posterior surface, and total cornea after SMILE, FS-LASIK, and FLEx surgeries. *Eye Contact Lens* 2016;42(6):358-365.

17 Kobashi H, Kamiya K, Shimizu K. Dry eye after small incision lenticule extraction and femtosecond laser-assisted LASIK: Meta-analysis. *Cornea* 2017;36(1):85-91.

18 Shen Z, Shi K, Yu Y, Yu X, Lin Y, Yao K. Small incision lenticule extraction (SMILE) versus femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK) for myopia: a systematic review and Meta-analysis. *PLoS One* 2016;11(7):e0158176.

19 Zhang Y, Shen Q, Jia Y, Zhou D, Zhou J. Clinical outcomes of SMILE and FS-LASIK used to treat myopia: a Meta-analysis. *J Refract Surg* 2016;32(4):256-265.

20 Egger M, Smith GD, Phillips AN. Meta-analysis: principles and procedures. *BMJ* 1997;315(7121):1533-1537.

21 Pogue J, Yusuf S. Overcoming the limitations of current meta-analysis of randomised controlled trials. *Lancet* 1998;351(9095):47-52.

22 Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, McQuay HJ. Assessing the quality of reports of randomized clinical trials: is blinding necessary? *Control Clin Trials* 1996;17(1):1-12.

23 Wells GA, Shea B, O'Connell D, Peterson J, Welch V, Losos M, Tugwell P. The Newcastle-Ottawa Scale (NOS) for assessing the quality of non-randomized studies in Meta-analysis. *Applied Engineering in Agriculture* 2014;18(6):727-734.

24 Begg CB, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. *Biometrics* 1994;50(4):1088-1101.

25 Egger M, Davey Smith G, Schneider M, Minder C. Bias in Meta-analysis detected by a simple, graphical test. *BMJ* 1997;315(7109):629-634.

26 Hu YK, Li WJ, Gao XW, Dong J, Guo YL. Effects of femtosecond laser small incision lenticule extraction on corneal wavefront aberration in the treatment of myopia. *Res Adv Ophtalmol* 2013;33(7):651-655.

27 Hu YK, Li WJ, Gao XW, Guo YL, Dong J. Comparison of small incision lenticule extraction and femtosecond laser assisted LASIK for myopia. *Guoji Yanke Zazhi (Int Eye Sci)* 2013;13(10):2074-2077.

28 Li K, Wang YL, Zhang CW, Wu J, Huang HY. Comparison of SMILE surgery and femotosecond laser LASIK for myopia. *Chin J Ophthalmol Vis Sci* 2014;16(8):478-482.

29 Li QH, Li YM, Hou HC, Song XY, Hu CE, Qi SW. Clinical comparative study of small incision lenticule extraction and femtosecond laser-assisted LASIK for high myopia. *Res Adv Ophthalmol* 2016;36(6):562-565.

30 Li WJ, Hu YK, Gao XW, Cao LP, Dong J, Guo YL, Cai Y. Evaluation of double-pass optical quality analysis system between SMILE and femtosecond LASIK for myopia. *Guoji Yanke Zazhi (Int Eye Sci)* 2014;14(11):1971-1974.

31 Qiao BD, Tie B, Zhao H, Ma SG. Comparison of the efficacy of femtosecond laser small incision extraction and femtosecond laser assisted LASIK. *Chin J Ocul Traum Occupat Eye Dis* 2015;37(4):261-265.

32 Wu ZQ, Wang Y, Zhang L, Geng WL, Jin Y, Zuo T. Wavefront analysis and comparison between small incision lenticule extraction and femtosecond laser *in situ* keratomileusis. *Zhonghua Yan Ke Za Zhi* 2015;51(3):193-201.

33 Ye M, Liao R, Liu C. Comparison of higher-order aberrations changes in anterior corneal surface after four refractive surgeries in myopia. *Acta Universitatis Medicinalis Anhui* 2014.

34 Zhang JM, Wang Y, Chen XQ, Li XJ, Xu LL, Dou R. Vector analysis and comprison of small incision lenticule extraction versus laser in-situ keratomileusis for low to moderate myopiac astigmatism. *Chin J Exp Ophthalmol* 2016;34(5):432-437.

35 Ang M, Ho H, Fenwick E, Lamoureux E, Htoon HM, Koh J, Tan D, Mehta JS. Vision-related quality of life and visual outcomes after small-incision lenticule extraction and laser *in situ* keratomileusis. *J Cataract Refract Surg* 2015;41(10):2136-2144.

36 Chan TC, Ng AL, Cheng GP, Wang Z, Ye C, Woo VC, Tham CC, Jhanji V. Vector analysis of astigmatic correction after small-incision lenticule extraction and femtosecond-assisted LASIK for low to moderate myopic astigmatism. *Br J Ophthalmol* 2016;100(4):553-559.

37 Denoyer A, Landman E, Trinh L, Faure JF, Auclin F, Baudouin C. Dry eye disease after refractive surgery comparative outcomes of small incision lenticule extraction versus LASIK. *Ophthalmology* 2015;122(4):669-676.

38 Li H, Wang Y, Dou R, Wei P, Zhang J, Zhao W, Li L. Intraocular pressure changes and relationship with corneal biomechanics after SMILE and FS-LASIK. *Invest Ophthalmol Vis Sci* 2016;57(10):4180-4186.

39 Li X, Wang Y, Dou R. Aberration compensation between anterior and posterior corneal surfaces after small incision lenticule extraction and femtosecond laser-assisted laser in-situ keratomileusis. *Ophthalmic Physiol Opt* 2015;35(5):540-551.

40 Lin F, Xu Y, Yang Y. Comparison of the visual results after SMILE and FS-LASIK for treating myopia. *J Refract Surg* 2014;30(4):248-254.

41 Sefat SM, Wiltfang R, Bechmann M, Mayer WJ, Kampik A, Kook D. Evaluation of changes in human corneas after femtosecond laser-assisted lasik and small-incision lenticule extraction (SMILE) using non-contact tonometry and ultra-high-speed camera (Corvis ST). *Curr Eye Res* 2016;41(7):917-922.

42 Shen Y, Chen Z, Knorz MC, Li M, Zhao J, Zhou X. Comparison of corneal deformation parameters after SMILE, LASEK, and femtosecond laser-assisted LASIK. *J Refract Surg* 2014;30(5):310-318.

43 Wu W, Wang Y. The correlation analysis between corneal biomechanical properties and the surgically induced corneal high-order aberrations after small incision lenticule extraction and femtosecond laser *in situ* keratomileusis. *J Ophthalmol* 2015;2015:758196.

44 Xu Y, Yang YB. A clinical study of small incision lenticule extraction for the correction of myopia and astigmatism. *University of Zhengjiang* 2014.

45 Agca A, Ozgurhan EB, Yildirim Y, Cankaya KI, Guleryuz NB, Alkin Z, Ozkaya A, Demirok A, Yilmaz OF. Corneal backscatter analysis by *in vivo* confocal microscopy: fellow eye comparison of small incision lenticule extraction and femtosecond laser-assisted LASIK. *J Ophthalmol* 2014;2014:265012.

46 Kim WS, Jo JM. Corneal hydration affects ablation during laser *in situ* keratomileusis surgery. *Cornea* 2001;20(4):394-397.

47 Patel S, Alio JL, Artola A. Changes in the refractive index of the human corneal stroma during laser *in situ* keratomileusis. Effects of exposure time and method used to create the flap. *J Cataract Refract Surg* 2008;34(7):1077-1082.

48 Vega-Estrada A, Alio JL, Arba Mosquera S, Moreno LJ. Corneal higher order aberrations after LASIK for high myopia with a fast repetition rate excimer laser, optimized ablation profile, and femtosecond laser-assisted flap. *J Refract Surg* 2012;28(10):689-696.

49 Pallikaris IG, Kymionis GD, Panagopoulou SI, Siganos CS, Theodorakis MA, Pallikaris AI. Induced optical aberrations following formation of a laser *in situ* keratomileusis flap. *J Cataract Refract Surg* 2002;28(10):1737-1741.

50 Kamiya K, Umeda K, Igarashi A, Ando W, Shimizu K. Factors influencing the changes in coma-like aberrations after myopic laser *in situ* keratomileusis. *Curr Eye Res* 2011;36(10):905-909.

51 Li M, Zhao J, Miao H, Shen Y, Sun L, Tian M, Wadium E, Zhou X. Mild decentration measured by a Scheimpflug camera and its impact on visual quality following SMILE in the early learning curve. *Invest Ophthalmol Vis Sci* 2014;55(6):3886-3892.

52 Reinstein DZ, Archer TJ, Randleman JB. Mathematical model to compare the relative tensile strength of the cornea after PRK, LASIK, and small incision lenticule extraction. *J Refract Surg* 2013;29(7):454-460.

53 Sinha Roy A, Dupps WJ Jr, Roberts CJ. Comparison of biomechanical effects of small-incision lenticule extraction and laser *in situ* keratomileusis: finite-element analysis. *J Cataract Refract Surg* 2014;40(6):971-980.

54 Nishimura M, Yan W, Mukudai Y, Nakamura S, Nakamasu K, Kawata M, Kawamoto T, Noshiro M, Hamada T, Kato Y. Role of chondroitin sulfate-hyaluronan interactions in the viscoelastic properties of extracellular matrices and fluids. *Biochim Biophys Acta* 1998;1380(1):1-9.

55 Riau AK, Angunawela RI, Chaurasia SS, Lee WS, Tan DT, Mehta JS. Early corneal wound healing and inflammatory responses after refractive lenticule extraction (ReLEx). *Invest Ophthalmol Vis Sci* 2011;52(9):6213-6221.

56 Holladay JT, Dudeja DR, Chang J. Functional vision and corneal changes after laser *in situ* keratomileusis determined by contrast sensitivity, glare testing, and corneal topography. *J Cataract Refract Surg* 1999;25(5):663-669.

57 Marcos S. Aberrations and visual performance following standard laser vision correction. *J Refract Surg* 2001;17(5):S596-601.

58 Stonecipher KG, Kezirian GM. Wavefront-optimized versus wavefront-guided LASIK for myopic astigmatism with the ALLEGRETTO WAVE: three-month results of a prospective FDA trial. *J Refract Surg* 2008;24(4):S424-430.